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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/754,379	01/05/2001	Wouter Cornelis Puijk	P51196US00	3527

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EXAMINER

ALEXANDER, LYLE

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/754,379

Applicant(s)

PUIJK ET AL.

Examiner

Lyle A. Alexander

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 1-2 and 9-11 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Pall et al.

Pall et al. teach in column 11 lines 21+ a HEMA grafted collection vessel that collects on the average 5.7 microliters of plasma. Example 19 teaches the collection vessel on a microtiter plate that has been read on the claimed "multiplicity of wells".

With respect claim 2 specifying the wells having a range of up to 5 microliters, the Office notes Pall et al. would be expected to contain volumes up to the claimed 5 microliters.

With respect to claims 9-11, Pall et al. meets all of the claimed structural requirements and inherently would be capable of performing the claimed functions. The method of intended use of an apparatus is of no patentable moment with respect to the apparatus claims.

The 9/15/05 amendments claim the well are within the range of 0.1-20 microliters. The Office maintains the teachings of column 11 lines 21+ teaching a collected volume of 5.7 microliters has been properly read on this new limitation.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pall et al.

See Pall et al. supra.

Pall et al. are silent to the claimed depth to diameter ratio of the wells and their density on the plate.

The court decided In re Dailey (149 USPQ 47) that "... the configuration of the container is a mere matter of choice and not significantly novel over ..." the art of record. The Office has read the claimed density of the well as the configuration of the plate. It is desirable to make the well as densely packed as possible to save on the cost of materials and space required for sample analysis.

It would have been within the skill of the art to modify Pall et al. and have a well density of 10-15 wells per square centimeter to gain the above advantages and because the configuration of the container is a mere matter of choice in view of Dailey above.

### ***Response to Arguments***

Applicant's arguments filed 9/15/05 have been fully considered but they are not persuasive.

Applicants' state the priority date of the presently claimed subject matter goes back to the PCT filed 11/20/1992. The Office will accept this statement as fact. However, it is suggested Applicants' supply a copy of this earliest document and point out where the support for the instant claims can be found.

Applicants' argue Pall fails to teach the claimed volume range and performs a calculate showing for Pall to collect a 5.7 microliter sample, 20.6 microliters must be collected. The instant claims only specify a volume of 0.1-20 microliters which is met by Pall and do not exclude additional steps taken by Pall to achieve the 5.7. microliter sample. The Office also notes, even if claim language were presented to exclude the additional steps taught by Pall, the taught sample of 20.6 microliters is sufficient close to the claimed 20 microliters that it would have been anticipated or be obvious. The Office also notes Pall teach in column 1 lines 46+ the instant invention is directed to a test device for the collection of sample between 3 and 30 microliters.

Applicants' state Pall fails to teach the claimed test device. The instant claim language "test device" is sufficiently broad to have been properly read on the device taught by Pall. Furthermore, Pall teaches in example 19 a multiwelled device that meets the spirit of the invention being discussed here.

Applicants' traverse the 35 USC 103 rejections of claims 3-8 over Pall on the basis the Office has used the "insidious ... hindsight syndrome". In the absence of a showing of unexpected results, the Office maintains the relative dimensions of the well would have been within the skill of the art.

### ***Conclusion***

This is a continuation of applicant's earlier Application No. 09/754,379. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL**

even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lyle A Alexander  
Primary Examiner  
Art Unit 1743

